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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/791,140 | 03/02/2004 | Ge Wang | 21087.0026U2 | 3175 |
| 23859 | 7590 | 08/12/2009 | | |
| Ballard Spahr Andrews & Ingersoll, LLP SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915 | | | EXAMINER LUONG, PETER | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/791,140 | Applicant(s) WANG ET AL. | |
| | Examiner Peter Luong | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-26 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: external excitation source term.

Claim Objections

2. Claims 1-11, 13-26, and 28-30 are objected to because of the following informalities: in claims 1 and 16 the limitation of “wherein the bioluminescent source distribution...” is unclear as to what further structural limitation is set forth and what further active method step is set forth. The limitation is unclear as to how it relates to the step of detecting optical/bioluminescent signals. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-11, 13-26, and 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed fails to disclose wherein the bioluminescent source distribution is produced based on a single- or multi-spectral radiative transfer equation without an external excitation source term. Applicant cites paragraphs 3, 45, and 54-60 for support

for the claim amendments, however, the Examiner points out that the specification does not provide referencing by paragraph numbers.

5. Claims 1-11, 13-26, and 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification as originally filed fails to enable one of ordinary skill in the art to make or use a single- or multi-spectral radiative transfer equation without an external excitation source term.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-11, 13-26, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warren et al. (Warren et al., "Combined Ultrasound and Fluorescence Spectroscopy for Physico-Chemical Imaging of Atherosclerosis". IEEE Transactions on Biomedical Engineering 42(2) (1995): 121-132) in view of Tomography – Definition from Dictionary.com.

9. With respect to claims 1 and 16, the publication of Warren et al. discloses a method and system for reconstructing a bioluminescent source distribution within an object (abstract, line 1) comprising imaging the object using a first imaging modality (page 125, col. 1, lines 12-13) to produce a first reconstructed image (figure 2, image reconstructed on oscilloscope), mapping optical properties (optical properties found on page 123, section B, lines 1-4) of the object to the first reconstructed image (page 126, col. 1, lines 54-58, data mapped to pixels), and detecting optical signals emitted from the object using an optical imaging modality (page 124, col. 2, lines 15-17) to produce a bioluminescent source distribution (page 126, col. 1, lines 54-58; page 123 Monte Carlo radiative transfer model), based on the mapped optical properties (page 126, col. 1, lines 54-58). Warren et al. also discloses a library of optical properties of the object (page 122, col. 2, lines 45-47 and Table 1) and a processor for mapping the optical properties of the object to the first reconstructed image (PC, figure 2).

10. Warren et al. does not teach the first imaging modality is a tomographic imaging modality. However, ultrasound is a well known tomographic imaging modality (see definition of tomography). Warren et al. only teaches A-mode imaging however B-mode imaging (tomographic ultrasound) is well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the

imaging modality of Warren et al. to a tomographic imaging modality as a substitution of one imaging modality for another is well within the skill level of one of ordinary skill in the art.

11. With respect to claims 2 and 17, Warren et al. discloses wherein the first reconstructed image shows two or three dimensional structural details of the object (A-mode image, page 125, col. 1, lines 12-13).

12. With respect to claims 3, 5, 9, 18, 20, and 24, Warren et al. discloses wherein the bioluminescent source distribution shows cross-sectional or volumetric views of the object or quantitative features of underlying source distributions of the object (page 122, col. 1, lines 27-30).

13. With respect to claims 4 and 19, Warren et al. discloses wherein the bioluminescent source distribution is reconstructed to represent multiple types of source distributions with various spectral characteristics (it is inherent that there would be multiple sources for a cross-sectional image to be reconstructed, page 122, col. 1, lines 27-30, furthermore, it is also inherent for the sources to have varying spectral characteristics, such as wavelengths).

14. With respect to claims 6 and 21, Warren et al. discloses wherein the bioluminescent source distribution is reconstructed using an iterative or analytical approach (page 123, section C).

15. With respect to claim 7 and 22, Warren et al. discloses wherein the step of detecting optical signals uses sensors (page 124, col. 2, lines 15-17).

16. With respect to claims 8 and 23, Warren et al. discloses wherein the step of detecting optical signals also uses optical path components (page 124, col. 2, lines 28-30).

17. With respect to claims 10 and 25, Warren et al. discloses wherein the optical properties include at least one of absorption coefficients, scattering coefficients, scattering anisotropy, indices of refraction, and features of underlying sources (page 123, section B, lines 1-4, and Table 1 shows scattering coefficients).

18. With respect to claims 11 and 26, Warren et al. discloses wherein the first imaging modality includes at least one of x-ray computed tomography, micro computed tomography, magnetic resonance imaging, and ultrasound (page 125, col. 1, lines 12-13).

19. With respect to claims 13 and 28, Warren et al. discloses segmenting the first reconstructed image into regions (A-mode imaging, page 125, col. 1, lines 12-13), wherein the step of mapping maps the optical properties to each segmented region of the image (page 126, col. 1, lines 54-58, mapped to pixels).

20. With respect to claim 14 and 29, Warren et al. discloses registering the first reconstructed image with the detected optical signals before producing the second reconstructed image (page 126, col. 1, lines 54-58).

21. With respect to claims 15 and 30, Warren et al. discloses wherein the step of registration uses a landmark-based method, a landmark free method, or an optical surface imager method (the catheter images the interior surface of an artery, page 125, col. 1, line 22-23).

Response to Arguments

Applicant's arguments with respect to claims 1-11, 13-26, and 28-30 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to the Examiner taking Official Notice is unclear. In the Office Action dated 2/3/2009 the Examiner has not stated he is taking Official Notice.

Applicant argues the prior art references fails to teach a bioluminescent imaging device configured for detecting bioluminescent signals. However, the Examiner respectfully disagrees with the applicant. As stated in the previous Office action, the Examiner's interpretation is that bioluminescence does not preclude the addition of external sources. Furthermore, applicant's disclosure indicates bioluminescence and fluorescence to be interchangeable (page 6, line 23).

With respect to the limitation of "wherein the bioluminescent source distribution is produced based on a single- or multi-spectral radiative transfer equation without an external excitation source term", the Examiner interprets the limitation as not further limiting the active method steps and/or does not set forth further structural limitation. The "wherein..." clause is directed to the source distribution and is unclear as to how it further limits the detection of optical signals. Therefore, the "wherein..." clause is not given patentable weight.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Luong whose telephone number is (571)270-1609. The examiner can normally be reached on Monday - Friday, 9:30 a.m. - 6:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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